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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,856	10/18/2005	Helen G Durkin	15727	4411

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EXAMINER	
RIDER, LANCE W	

ART UNIT	PAPER NUMBER
4131	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,856	DURKIN ET AL.	
	Examiner	Art Unit	
	LANCE RIDER	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/07/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/13/2008 and 12/03/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golub, et al, U.S. Patent 4,666,897.

Claims 1 and 3-14 are drawn to a method for reducing the IgE concentration in the blood of a patient suffering from a disease and administering a therapeutically effective amount of an antibiotic. The antibiotics specifically claimed in claims 1, and claims 3-14 are of the tetracycline family, drawn to the specific antibiotics and mixtures thereof including minocycline, doxycycline, and tetracycline. The prior art teaches the administration of the antibiotics minocycline, doxycycline, and tetracycline, disclosed on page 7, column 3, paragraph 1. The prior art also discloses on page 6, column 2, lines 40-45 that these antibiotics are used for the treatment of inflammatory associated diseases such as rheumatoid arthritis, and periodontal disease.

Claim 1, and claims 3-14 are drawn to "a method for reducing the IgE concentration in the blood". As both the cited prior art and the claims teach the use of these antibiotics for the treatment of inflammatory diseases, the IgE concentrations of patients must necessarily be reduced in the prior art as well. Thus the current application provides no new information that was not already obvious to one of ordinary skill in the art at the time of the invention.

Though the prior art does not teach the precise mixtures of antibiotics as claimed in claims 6 and 8, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. In the instant case applicant is making combinations of tetracycline, doxycycline, and minocycline. All of these

compounds are known to have similar core structures, are in the same class of antibiotics, and are often substitutes for one another in the treatment of diseases. The idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). **MPEP 2144.06**.

Claims 10, 12, and 13 are drawn to dosages of the drugs ranging from either 1-300 mg/day or 25-100 mg. The prior art teaches on page 7, column 4, line 11, dosage ranges of 200-500 md/day for tetracycline, and on page 7, column 4, line 29, dosage ranges of 150-900 mg/day for doxycycline.

Claims 9 and 11 are drawn to dosage forms of either paranterally or orally administered forms of the antibiotics. Claim 14 is also drawn to a composition which further comprises a pharmaceutically acceptable carrier. The prior art teaches on page 7, column 4, lines 33-47, the oral and parenteral administration of these antibiotics in the form of “tablets, caplets, or elixirs and the like”.

It is also noted for claims 9-13 that it would be routine to optimize the administration form and dosage of the drugs administered depending upon the age of the patient, weight of the patient, the species of animal being treated, the condition being treated, and the severity of said condition. The optimization of the dosage, and dosage form of the drugs administered, and thereby the amounts administered would be obvious to one of ordinary skill in the art at the time of the invention, and therefor would be considered obvious.

Claim 2, and claims 15-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golub, et al, U.S. Patent 4,666,897 as applied to claims 1 and 3-14 above, and further in view of (Joks, et al., J. Allergy Clin. Immunol. 1998, 101:562).

Claim 2 and claims 15-26 are drawn to a method for reducing the IgE concentration in the blood of a patient suffering from **asthma** and administering a therapeutically effective amount of an antibiotic. The antibiotics specifically claimed in claims 2, and claims 15-26 are of the tetracycline family, drawn to the specific antibiotics and mixtures thereof including minocycline, doxycycline, and tetracycline. (Golub, et al, U.S. Patent 4,666,897), teaches the administration of the antibiotics minocycline, doxycycline, and tetracycline, disclosed on page 7, column 3, paragraph 1. (Golub, et al, U.S. Patent 4,666,897), also discloses on page 6, column 2, lines 40-45 that these antibiotics are used for the treatment of inflammatory associated diseases such as rheumatoid arthritis, and periodontal disease. (Golub, et al, U.S. Patent 4,666,897), though disclosing the use of tetracycline antibiotics for the treatment of inflammatory diseases, does not specifically disclose the use of these compounds for the treatment of **asthma**. (Joks, et al., J. Allergy Clin. Immunol. 1998, 101:562) teaches on page 562 paragraphs 1 and 2, the use of the tetracycline antibiotic minocycline for the treatment of the inflammatory disease **asthma**. It would therefor have been obvious to one of ordinary skill in the art at the time of the invention to use the common treatment for inflammatory diseases disclosed by (Golub, et al, U.S. Patent 4,666,897) in the

treatment of another inflammatory disease asthma, as disclosed by (Joks, et al., J. Allergy Clin. Immunol. 1998, 101:562).

Claim 2, and claims 15-26 are drawn to "a method for reducing the IgE concentration in the blood". As both the cited prior art and the claims teach the use of these antibiotics for the treatment of inflammatory diseases, the IgE concentrations of patients must necessarily be reduced in the prior art as well. Thus the current application provides no new information that was not already obvious to one of ordinary skill in the art at the time of the invention.

Though the prior art does not teach the precise mixtures of antibiotics as claimed in claims 19 and 20, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. In the instant case applicant is making combinations of tetracycline, doxycycline, and minocycline. All of these compounds are known to have similar core structures, are in the same class of antibiotics, and are often substitutes for one another in the treatment of diseases. The idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). **MPEP 2144.06**.

Claims 21, 22, 24, and 25 are drawn to dosages of the drugs ranging from either 1-300 mg/day or 25-100 mg. The prior art teaches on page 7, column 4, line 11, dosage ranges of 200-500 md/day for tetracycline, and on page 7, column 4, line 29, dosage ranges of 150-900 mg/day for doxycycline.

Claims 21 and 23 are drawn to dosage forms of either paranterally or orally administered forms of the antibiotics. Claim 26 is also drawn to a composition which further comprises a pharmaceutically acceptable carrier. The prior art teaches on page 7, column 4, lines 33-47, the oral and parenteral administration of these antibiotics in the form of “tablets, caplets, or elixirs and the like”.

It is also noted for claims 21-26 that it would be routine to optimize the administration form and dosage of the drugs administered depending upon the age of the patient, weight of the patient, the species of animal being treated, the condition being treated, and the severity of said condition. The optimization of the dosage, and dosage form of the drugs administered, and thereby the amounts administered would be obvious to one of ordinary skill in the art at the time of the invention, and therefor would be considered obvious.

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Kuzin I. I, et al., Inter. Immu., 12:921-931).

Claims 27-29 are drawn to a method for monitoring the effectiveness of a drug (tetracycline) in lowering the concentration of IgE in the plasma of a mammal suffering from a disease. The claims recite the active steps of determining the concentration of IgE in the plasma of a mammal, administering a drug which lowers said concentration, making a second determination of the IgE concentration in the plasma of the mammal subsequent to said administration, and comparing the values of the first and second administration.

(Kuzin I. I, et al., Inter. Immu., 12:921-931) teach on page 923, in the results, paragraphs 1 and 2 and in figure 2 on page 924, a method for monitoring the effects of doxycycline (a tetracycline) in lowering the concentration of IgE in mouse splenocytes. Though not specifically drawn to the use of testing the effects in the plasma of a diseased mammal, the method recites the same active steps of determining the concentration of IgE, administering a drug which lowers said concentration, making a second determination of the IgE concentration subsequent to said administration, and comparing the values of the first and second administration. It would therefor have been obvious to one of ordinary skill in the art at the time of the invention to have used this same procedure for monitoring the change in IgE concentration in the plasma of a diseased individual as well as in mouse splenocytes.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LANCE RIDER whose telephone number is (571)270-1337. The examiner can normally be reached on Monday through Friday, 7:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LANCE RIDER/
Examiner, Art Unit 4131

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624